

In the Specification (clean copy as amended)

Please replace paragraph 0014 on page 7 with the following:

2 [The present invention reduces the increased diastolic pressure that can occur as part of the clinical syndrome referred to as Congestive Heart Failure (CHF). Passive and semi-passive devices to reduce left ventricular end-diastolic pressure are disclosed, and in preferred embodiments, a shunt-type device allows a small volume of blood to be released from the left ventricle to reduce the pressure. Certain embodiments use a passive check-valve that allows flow only above a given threshold pressure, while others use a passive check-valve that allows flow only within a window between a lower pressure threshold and a higher-pressure threshold. Embodiments employing check valves prevent shunting during left ventricular systole. Alternatively, semi-passive embodiments have a valve activated by and external signal, such as an intra-corporeal electrical battery or an externally coupled energy source. A third type of preferred embodiment of the invention employs a device such as a pump to actively move blood, with the intent of preventing further deterioration of the patient's heart failure or allowing for some reversal of the heart failure. For example in patients presenting with diastolic heart failure (DHF) the present invention prevents this occurrence by reducing diastolic pressures in the left atrium below the excessive levels that would otherwise have caused pulmonary edema.

Please replace paragraph 0017 on page 8 with the following:

02 [FIG. 2 is a side elevation view, in cross-section as shown by lines 2-2 in FIG.1, illustrating the placement of the shunt shown in FIG. 1 in a septum, and showing diagrammatically the use of a pump to augment flow in certain embodiments; and

Please replace paragraph 0019 on page 8 with the following:

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Referring now to FIG. 1, there is shown a perspective view of a first embodiment of a shunt 100 made in accordance with the present invention. The shunt 100 is comprised of a fixation element 110, which is shown as a planar circular element. It will be understood, however, that the fixation element 110 can be circular, polygonal, spiral or many other shapes. Moreover, the fixation element can lie in a single plane or be curved in multiple planes, such as in a helical configuration. It can be constructed of a variety of materials that offer the elastic range and spring-like characteristics that will enable passage through a catheter lumen, or through the lumen of another implantation assistance device, in a relatively straightened configuration and then recovery of its full fixation configuration shape. In certain embodiments, the fixation element can be made of reduced size and then expanded through the use of shape-memory alloys (SMA's), such as nickel-titanium (NiTi, also known as nitinol), that change shape in response to temperature changes and which are fabricated such that the temperature change from below body temperature to body temperature causes the shape conversion necessary for implantation. If SMA materials are not used, suitable materials include super-elastic metals, such as NiTi, or stainless steel, such as the alloy Elgiloy®, commonly used for medical implants. Additionally, polymeric materials can be used to form the fixation element or as a coating over a metallic core. The fixation element may be coated and/or textured as so as to increase its biocompatibility or to increase the degree to which it quickly becomes endothelial/zed, which may be desired in some implantation conditions.

Please replace paragraph 0024 on page 10 with the following:

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In accordance with the present invention, the device may or may not include the valve element 130, since in certain patients or to treat certain conditions a valve would add complexity while not providing necessary functionality. Similarly, depending upon the circumstances of use, the valve element 130 may be either passive (actuated by the force of blood) or active (actuated by some other portion of the device). In active valve

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embodiments, the valve element 130 may include electric or electromagnetic elements that can be selectively actuated to open and close the valve element 130 or, if the valve element is designed for gradual opening and closing, move the valve element 130 between a first position and a second position. In some embodiments, the valve will be chosen and designed so that it responds only upon certain conditions occurring within the heart, such as the following: absolute left atrial pressure, differential atrial pressure, other intra-cardiac pressures, other cardiovascular pressures, or other physiological conditions that might correlate to an exacerbated state of diastolic heart failure, such as blood oxygen saturation or pH. In such embodiments, response to any given pressure or differential pressure will imply that a portion of the implanted device is in fluid communication with the relevant pressure source or sources. These embodiments will provide robust and reliable functionality by being mechanical and operating with signal inputs. All shunts, whether they include a valve or not can be further enhanced by including a check-valve that will prevent backflow. Those of skill in the art will appreciate that it is typically desirable to prevent flow from the right heart to the left heart, and thus one or more check valves can be appropriately placed. A double-check valve allows blood pressure above a lower limit but below a higher limit to actuate the valve, thus in a preferred embodiment, shunting blood from the left side to the right side only during a period of diastole.

Please replace paragraph 0032 on page 13 with the following:

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The pressure/flow/volume requirements of the various embodiments of the present invention will be determined using methodologies similar to those used to design a Left Ventricular Assist Device (LVAD) but with certain distinctly different flow requirements, rather than the intent of supporting systemic circulation requirements found in a LVAD. Thus, certain shunts made in accordance with the present invention can use designs and dimensions that would not be appropriate or adequate for an LVAD. Patients with heart failure dominated by systolic dysfunction exhibit contraction

abnormalities, whereas those in diastolic dysfunction exhibit relaxation abnormalities. In most patients there is a mixed pathophysiology. Normal pulmonary venous pressure (PVP) necessary for the normal LV to adequately fill and pump is less than 12 mmHg. Patients with systolic dysfunction have larger LV volume to maintain SV and may need increased PVP to fill (mixed systolic diastolic dysfunction). Patients with diastolic dysfunction need increased PVP for the LV to fill and adequately pump.
